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VIA ELECTRONIC MAIL

North Carolina Office of Administrative Hearings
Rules Review Commission
1711 New Hope Church Road
Raleigh NC, 27609
rrc.comments@oah.nc.gov

Board of Pharmacy Rulemaking Coordinator
Clinton R. Pinyan
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Greensboro, NC 27420
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***RE: SUBMISSION OF WRITTEN COMMENTS CONCERNING PERMANENT
RULE 21 NCAC 46.1417 AND .1816***

Dear Rules Review Commission (the "Commission"),

We are writing to on behalf of several clients we represent in the pharmacy industry to request the Commission to object to the above referenced Rules in accordance with G.S. 150B-21.10. Boesen & Snow represents numerous pharmacies, pharmacists, and pharmacy technicians across the country that service North Carolina residents (herein referred to "pharmacy stakeholders").

The North Carolina Board of Pharmacy (the "Board") conducted a hearing for the repeal of 21 NCAC 46.1417, Remote Medication Order Processing Services, and an amendment to 21 NCAC 46.1816, Procedures for Centralized Processing of Prescription Orders on July 20, 2021. Many industry stakeholders voiced concerns and comments to the Board during this meeting. North Carolina Board of Pharmacy Meeting Minutes (July 20, 2021), available at <http://www.ncbop.org/about/Agendas%20and%20Minutes/Minutes07.21.pdf>. As a result, the Board did not adopt the rules at this meeting. The Board did not discuss this rule changes at the September 2021 Board Meeting. On November 9, 2021, the Board publicized revisions to the proposed rules declaring that these changes were not substantive and thus republication and public comment regarding the proposal was not required (the "revised rule"). North Carolina

Board of Pharmacy Meeting Minutes (September 9, 2021), available at <http://www.ncbop.org/about/Agendas%20and%20Minutes/Minutes11.21.pdf>. On December 9, 2021, the Board submitted the rule to the Commission. Based on comments submitted to the Commission, the Board requested an extension to the Commission to delay review of the rules. On January 18, 2022, the Board met and reviewed the comments to the commission and approved the rule to go forward to the Commission without going to public comment.

The revised rule presented at the November Board Meeting primarily eliminated the requirement that out-of-state pharmacy technicians providing inter-pharmacy remote medication order entry services be individually registered in North Carolina. The revised rule also provides an alternative to individual licensure in North Carolina for out-of-state pharmacists performing inter-pharmacy remote medication order entry services through a continuous monitoring service administered by the National Association of Boards of Pharmacy ("NABP") through a program called "NABP Verify." ~~Conveniently, the On January 13, 2022, NABP published on January 13, 2022,~~ five days before the Board meeting, ~~the NABP published~~ a short memo about the NABP Verify program on their website, available at: [January 13, 2022 - National Association of Boards of Pharmacy \(nabp.pharmacy\)](http://www.nabp.pharmacy)

The North Carolina Administrative Procedures Act, N.C.G.S.A. § 150B-21.2(g), states that an adopted rule differs substantially from a proposed rule if it does one or more of the following: "(1) Affects the interests of persons who, based on the proposed text of the rule published in the North Carolina Register, could not reasonably have determined that the rule would affect their interests. (2) Addresses a subject matter or an issue that is not addressed in the proposed text of the rule. (3) Produces an effect that could not reasonably have been expected based on the proposed text of the rule." Here, the Board's addition of the NABP Verify language is a substantial difference.

The NABP Verify language affects the interests of persons who could not reasonably have determined that the rule would affect their interests. Out-of-state pharmacists, or out-of-state pharmacy permit holders, could not have reasonably anticipated this change when providing comment in July regarding the original proposed rule. The original proposed rule made no mention or reference to the NABP or any other third-party verification program. Little is known about the NABP Verify program. The Board chooses to incorporate the program by reference into the rule while pharmacy stakeholders that will bear the cost and compliance requirements associated with NABP Verify are left trying to determine what this requirement entails. The NABP does not have an informational website or description regarding registration or compliance with this program. Furthermore, the cost NABP indicates will be associated with this program is \$50/pharmacist, which, compounded over numerous pharmacists could be quite costly to out-of-state pharmacy permit holders. It is also possible these fees could easily change in the future.

The NABP Verify language addresses a subject matter or an issue that is not addressed in the proposed text of the rule. As previously mentioned, the original proposed rule made no mention or reference to the NABP or any other third-party verification program. The Board did not provide pharmacy stakeholders any opportunity to comment on this entirely new subject matter.

Finally, the NABP Verify produces an effect that could not reasonably have been expected based on the proposed text of the rule. Pharmacy stakeholders will be held responsible for payment of any registration fees associated with the NABP Verify program, as well as any additional compliance requirements, such as reporting or monitoring that the program may require. Little information is known about the NABP Verify program and Pharmacy stakeholders are concerned the program could present fiscal impacts, negative implications with other state pharmacy boards if the pharmacy stakeholder does not participate in the program or chooses to stop participating in the program, and onerous compliance requirements may present. Pharmacy stakeholders could not reasonably have been expected based on the proposed text of the rule to address these concerns.

For the aforementioned reasons, the North Carolina Board of Pharmacy violated the North Carolina Administrative Procedures Act, N.C.G.S.A. § 150B-21.2(g), by not publishing the text of the proposed different rule in the North Carolina Register and not accepting comments on the proposed different rule.

Furthermore, we argue that the Commission should deny the above referenced Rule because it conflicts with the requirements set forth in N.C.G.S.A. § 150B-19.1(a). Specifically, the Commission should find that the proposed rules create an unnecessary burden on pharmacies and does not provide evidence this change will serve the public interest for North Carolina residents. The proposed rule significantly increases the burden for out-of-state pharmacies by requiring them to ensure compliance with the licensure and registration of all pharmacy personnel within the home state of the pharmacy, as well as the State of North Carolina. Some pharmacies may find this unnecessary barrier too cumbersome and choose to discontinue servicing North Carolina patients. As previously mentioned, the pharmacy stakeholders may also find the NABP Verify program to be too cost-restrictive if numerous pharmacists must be registered and associated fees change. Moreover, pharmacy stakeholders cannot determine if the NABP Verify program is based on sound scientific, technical, economic, and other relevant information, as there is little information regarding the NABP Verify program. Pharmacy stakeholders may be subject to the whims of the NABP and their ability to change the NABP Verify program as an unregulated entity.

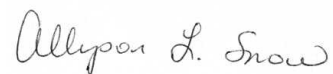
The rule also appears to be outside the scope of the Board of Pharmacy's authority as mandating out-of-state pharmacies to license or register all pharmacy personnel in North Carolina is not expressly authorized by Federal or State law. 21 N.C. Admin. Code 46.1607(d), North Carolina's "out-of-state pharmacies" regulation, further supports this interpretation which merely provides that "[a]n out-of-state pharmacy shall comply with the statutes and regulations of the state in which the pharmacy is located."

On behalf of our many pharmacy stakeholders we request that the Commission object to the amendments to 21 NCAC 46.1816 so that the public and relevant stakeholders may have an opportunity to review and comment on the rules as mandated by the North Carolina Administrative Procedure Act.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark D. Boesen". The signature is stylized with a large, bold "M" and "B".

Mark D. Boesen, Pharm.D., J.D.
Attorney

A handwritten signature in black ink, appearing to read "Allyson L. Snow". The signature is written in a cursive, flowing style.

Allyson Snow, J.D.
Attorney